

JUN 1 - 2005

K051167

1/5

Attachment V

510(k) Summary

1. General Information

Submitter: AllMed Systems Inc.
9232 Klemetson Drive
Pleasanton CA 94588

Phone: 925-468-0433

Fax 925-399-5984

Contact Person Peter Allen

Date Prepared 4th May 2005

2. Names

Device Name Revolix Family of Laser Systems including the Revolix
and Revolix Jr

Common Name 2.01micron Laser System

Classification Name Laser Surgical Instrument and accessories

3. Predicate Device

Lumenis/Coherent Medical – VersaPulse Ho:YAG
Trimeddyne Omnipulse Max 80 watt

4. Product Description

The Revolix and Revolix Jr are diode pump solid state surgical laser system operating at a wavelength of 2.01 micron. The purpose of the laser is the ablation, coagulation, dissection and resection of soft tissue. The laser is designed for open surgery, laparoscopic and surgical applications in aqueous media. The

laser power is delivered via standard silica laser fibers. The distal tip is guided by a handpiece or endoscopic/laparoscopic surgical instrument.

It consists of:

- Laser Console with Internal Computer
- Control Panel and Display
- A fiber optic delivery system
- Footswitch

5. Indications for Use

Arthroscopy

Arthroscopy/orthopedic surgery (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including

- Meniscectomy
- Plica removal
- Ligament and Tendon release
- Contouring and sculpting of articular surfaces
- Debridement of inflamed synovial tissue (synovectomy)
- Loose body debridement
- Chondromalacia and tears
- Lateral retinacular release
- Capsulectomy in the knee
- Chondroplasty in the knee

Disectomy including

Percutaneous vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine; open and arthroscopic spine procedures: foraminotomy

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas

Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

- Laryngeal Lesions
- Airway obstructions including carcinoma
- Polyps and Granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)

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Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation
Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

Dermatology and Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas
- Lesions of skin and subcutaneous tissue
- Skin tags
- Plantar warts

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy

Hepatectomy
Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy
Pilonidal Cystectomy
Resection of lipoma
Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Stasis Ulcer
Biopsy

6. Rationale for Substantial Equivalence

The Revolix and RevoLix Jr laser system with fiber optic delivery devices share the same intended use, indications for use, similar design features and functional features and therefore are substantially equivalent to the Lumenis VersaPulse Laser

7. Conclusion

The Revolix and RevoLix Jr Laser System with fiber optic delivery devices were found to be substantially equivalent to similar currently marketed and predicate surgical laser systems and delivery devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2005

Mr. Peter N. Allen
President
AllMed Systems Incorporated
9232 Klemetson Drive
Pleasanton, California 94588

Re: K051167

Trade/Device Name: RevoLix and RevoLix Jr
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 4, 2005
Received: May 5, 2005

Dear Mr. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

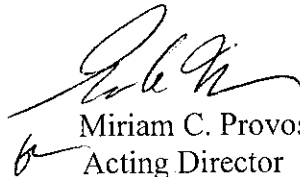
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Peter N. Allen

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost", is written over the typed name.

Miriam C. Provost, Ph.D.
Acting Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: *K051167*

Device Name: RevoLix and RevoLix Jr

Indications For Use:

The Revolix and RevoLix Jr laser systems and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Urethral Strictures

Bladder Neck Incisions (BNI)

Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors.

Ablation of Benign Prostatic Hypertrophy (BHP),

Transurethral incision of the prostate (TUIP)

Laser Resection of the Prostrate (HoLRP)

Laser Enucleation of the Prostate (HoLEP)

Laser Ablation of the Prostate (HoLAP)

Condylomas

Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

Appendectomy

Polyps

Biopsy

Gall Bladder calculi

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Director, Center for Devices and Radiological Controls

Indications for Use

510(k) Number: K051167

Device Name: RevoLix and RevoLix Jr

Indications For Use:

- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue


- Laryngeal Lesions
- Airway obstructions including carcinoma
- Polyps and Granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K051167

Device Name: RevoLix and RevoLix Jr

Indications For Use:

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)

Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation

Soft tissue excision procedures such as excisional conization of the cervix

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

Endonasal/sinus Surgery
Partial turbinectomy
Polypectomy
Dacryocystorhinostomy
Frontal Sinusotomy
Ethmoidectomy
Maxillary antrostomy
Functional endoscopic sinus surgery
Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
Tonsillectomy
Adenoidectomy

Dermatology and Plastic Surgery

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 3 of 5

William J. Bernstein
Biological Devices

K051167

Indications for Use

510(k) Number: *K051167*

Device Name: RevoLix and RevoLix Jr

Indications For Use:

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

Basal Cell Carcinomas
Lesions of skin and subcutaneous tissue
Skin tags
Plantar warts

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

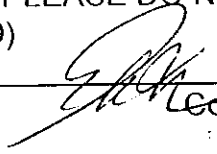
Cholecystectomy
Lysis of adhesion
Appendectomy
Biopsy
Skin incision
Tissue dissection
Excision of external tumors and lesions
Complete or partial resection of internal organs, tumors and lesions
Mastectomy
Hepatectomy
Pancreatectomy
Splenectomy
Thyroidectomy
Parathyroidectomy
Herniorrhaphy
Tonsillectomy
Lymphadenectomy
Partial Nephrectomy

Prescription Use *X*
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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NEEDED)

 Concurrence of CDRH, Office of Device Evaluation (ODE)

Regenerative
Medical Devices

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Indications for Use

510(k) Number: K051167

Device Name: RevoLix and RevoLix Jr

Indications For Use:

Pilonidal Cystectomy
Resection of lipoma
Debridement of Decubitus Ulcer
Hemorrhoids
Debridement of Stasis Ulcer
Biopsy

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

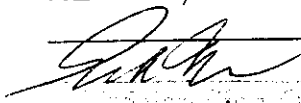
Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including
Percutaneous Laser Disc Decompression/Discectomy
Foraminoplasty
Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative
and Neurological Devices

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